IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HQ SPECIALTY PHARMA CORP. and WG CRITICAL CARE, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 21-1714 (MN)
FRESENIUS KABI USA, L.L.C.,	)	
Defendant.	)	

MEMORANDUM OPINION

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July 2, 2025
Wilmington, Delaware

NOREIKA, U.S. DISTRICT JUDGE:

From August 26 to 30, 2024, the Court presided over a five-day jury trial in this patent case (*see* D.I. 285, 286, 287, 288, 289 (together, "Tr.")) between Plaintiffs HQ Specialty Pharma Corporation ("HQ") and WG Critical Care, LLC (together, "Plaintiffs"), and Defendant Fresenius Kabi USA, LLC ("Fresenius" or "Defendant"). Defendant stipulated to infringement of claims 1-3 of U.S. Patent No. 10, 130,646 ("the '646 patent"), if those claims are valid and enforceable.[1] (D.I. 90). At the end of the trial, the jury found that Defendant (1) had not proved that claim 1 of the '646 patent is invalid for improper inventorship, (2) had proved that claims 2 and 3 of that patent are invalid on that basis, and (3) had not proved that any of claims 1, 2, or 3 of the '646 patent is invalid for obviousness. (D.I. 261).

Now pending before the Court are four post-trial motions from the parties: (1) Plaintiffs' motion for judgment as a matter of law (D.I. 295); (2) Defendant's motion for judgment as a matter of law, or, in the alternative, a new trial (D.I. 293); (3) Plaintiffs' motion to correct inventorship (D.I. 267); and (4) Plaintiffs' motion to amend the judgment (D.I. 295). For the reasons set forth below, the Court will (i) GRANT-IN-PART and DENY-IN-PART Plaintiffs' motion for judgment as a matter of law; (ii) DENY Defendant's motion in its entirety; (iii) GRANT Plaintiffs' motion to correct inventorship; and (iv) GRANT Plaintiffs' motion to alter the judgment.

[1] Defendant asserted that the '646 patent is unenforceable based on inequitable conduct. After a bench trial on that issue, the Court found that Defendant failed to prove inequitable conduct by clear and convincing evidence. (D.I. 314, 315).

I. BACKGROUND

The '646 patent is owned by HQ and names as the sole inventor Joseph Pizza. (*See* JTX-1 at 2). The patent is entitled, "Calcium Gluconate Solutions in Flexible Containers" and claims a terminally sterilized calcium gluconate solution packaged in a free-flex plastic bag. (*Id.*). In other words, the invention is a ready-to-use bag for hospitals to administer intravenous ("IV") calcium gluconate treatment to patients.

Plaintiffs filed this action on December 3, 2021, alleging that Fresenius' calcium gluconate bag product ("the Accused Product") infringes claims 1, 2, and 3 of the '646 patent (collectively, "the Asserted Claims"). (D.I. 1). Fresenius counterclaimed for invalidity and unenforceability, and later stipulated to infringement. (D.I. 26, 90). From August 26 to 30, 2024, the Court presided over a jury trial. (*See* Tr.). At trial, Plaintiffs sought to prove damages, while Fresenius endeavored to invalidate the Asserted Claims for obviousness and improper inventorship. At the conclusion of trial, the jury found that Defendant had failed to prove, by clear and convincing evidence, that the Asserted Claims are obvious and that claim 1 of the '646 patent is invalid for improper inventorship. (D.I. 261 at 2-3). The jury determined, however, that Defendant had proved that dependent claims 2 and 3 are invalid for lack of proper inventorship. (*Id.*). The jury did not award damages because the parties agreed that the verdict form should instruct the jury to address damages only if all claims were not found to be invalid.[2] (*See* Tr. at 885:13-893:23). On September 16, 2024, the Court entered judgment on the jury verdict. (D.I. 277).

On September 11, 2024, Plaintiffs moved to correct inventorship pursuant to 35 U.S.C. § 256. (D.I. 267). The motion was fully briefed as of October 8, 2024. (D.I. 268, 281, 292). On October 15, the parties filed their motions for judgment as a matter of law.

[2] Plaintiffs' claim for damages was less than $100,000, and Plaintiffs represented that the primary relief sought is an injunction. (*See* Tr. at 735:14-21; 889:4-20; 1015:11-16).

(D.I. 293, 295). Those motions were fully briefed as of November 6, 2024. (D.I. 294, 296, 304, 305, 307, 308). The Court now addresses the motions in turn.

II. LEGAL STANDARDS

A. Judgment as a Matter of Law

Judgment as a matter of law may be entered against a non-moving party if the Court "finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on [an] issue." Fed. R. Civ. P. 50(a)(1). A motion for judgment as a matter of law "should be granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 373 (3d Cir. 2016) (quoting *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993)). "Judgment as a matter of law is proper only if the record is critically deficient of the minimum quantum of evidence needed to support the verdict." *Washington v. Gilmore*, 124 F.4th 178, 185 (3d Cir. 2024) (internal quotation marks omitted). It is a remedy to be invoked "sparingly." *CGB Occupational Therapy, Inc. v. RHA Health Servs. Inc.*, 357 F.3d 375, 383 (3d Cir. 2004); *Marra v. Philadelphia Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007).

Following a jury trial, a renewed motion for judgment as a matter of law under Rule 50(b) may be granted only if the movant demonstrates "that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied by the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (citation modified). Substantial evidence is such relevant evidence that a reasonable mind might accept as adequate to support the finding under review. *Enplas Display Device Corp. v. Seoul Semiconductor Co.*, 909 F.3d 398, 407 (Fed. Cir. 2018).

In determining whether substantial evidence supports the jury verdict, the Court may not make credibility determinations, weigh the evidence, or substitute its own conclusions for those of the jury where the record evidence supports multiple inferences. *See Rodriquez v. Se. Pa. Trans. Auth.*, 119 F.4th 296, 298 (3d Cir. 2024); *Avaya*, 838 F.3d at 373. Moreover, in the Third Circuit, when the movant bears the burden of proof on an issue, judgment as a matter of law is appropriate only if "there is insufficient evidence for permitting any different finding." *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976) (citations omitted).

B. Motion for a New Trial

"[A]fter a jury trial," the Court may grant a new trial "to any party" on "all or some of the issues" for "any reason for which a new trial has heretofore been granted" in federal court actions at law. Fed. R. Civ. P. 59(a)(1)(A). Common grounds for a new trial are: "(1) where the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) where newly-discovered evidence exists that would likely alter the outcome of the trial; (3) where improper conduct by an attorney or the court unfairly influenced the verdict; or (4) where the jury's verdict was facially inconsistent." *Ateliers de la Haute-Garonne v. Broetje Automation-USA Inc.*, 85 F. Supp. 3d 768, 775 (D. Del. 2015).

Whether to grant a new trial is a question committed to the Court's discretion. *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36 (1980). Unlike the standard for judgment as a matter of law, on a motion for a new trial, "the Court need not view the evidence in the light most favorable to the verdict winner." *Ateliers*, 85 F. Supp. 3d at 776. "Nevertheless, new trials because the verdict is against the weight of the evidence are proper only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be

overturned or shocks [the] conscience." *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1353 (3d Cir. 1991).

C. Motion to Correct Inventorship

"Inventorship is a question of law based on underlying facts." *Blue Gentian, LLC v. Tristar Prods., Inc.*, 70 F.4th 1351, 1358 (Fed. Cir. 2023); *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998). To be valid, "a patent [must] accurately list the correct inventors of a claimed invention." *Pannu*, 155 F.3d at 1349. "All inventors, even those who contribute to only one claim or one aspect of one claim of a patent, must be listed on that patent." *Vapor Point LLC v. Moorhead*, 832 F.3d 1343, 1348-49 (Fed. Cir. 2016). "[I]f nonjoinder of an actual inventor is proved by clear and convincing evidence, a patent is rendered invalid." *Pannu*, 155 F.3d at 1349 (internal citations omitted).

That shortcoming may be remedied, however. *See Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1376 (Fed. Cir. 2020) ("[A] patent cannot be invalidated if inventorship can be corrected instead."). "Under 35 U.S.C. § 256, a district court may order correction of inventorship when it determines that an inventor has been erroneously omitted from a patent." *Blue Gentian*, 70 F.4th at 1357. "[T]he party seeking correction of inventorship must show by clear and convincing evidence that a joint inventor should have been listed." *BearBox LLC v. Lancium LLC*, 125 F.4th 1101, 1117 (Fed. Cir. 2025).

Correction may only occur "on notice and hearing of all parties concerned," 35 U.S.C. § 256(b), and any request to do so must be accompanied by statements from the relevant parties "either agreeing to the change of inventorship or stating that he or she has no disagreement in regard to the requested change." 37 C.F.R. § 1.324(b)(1). If the Court accepts and so-orders the correction, "the [USPTO] Director shall issue a certificate accordingly." 35 U.S.C. § 256(b).

D. Motion to Alter or Amend a Judgment

"Rule 59(e) allows a litigant to file a motion to alter or amend a judgment." *Banister v. Davis*, 590 U.S. 504, 507 (2020) (internal quotation marks omitted). "[T]he Rule was adopted to make clear that the district court possesses the power to rectify [any issues] in the period immediately following the entry of judgment." *White v. New Hampshire Dept. of Emp't Sec.*, 455 U.S. 445, 450 (1982) (citation modified). "A proper Rule 59(e) motion must rely on one of three grounds: (1) an intervening change in controlling law; (2) the availability of new evidence; or (3) the need to correct clear error of law or prevent manifest injustice." *In re Processed Egg Prods. Antitrust Litig.*, 962 F.3d 719, 729 (3d Cir. 2020) (citation modified). "Rule 59(e) is not a vehicle for reopening judgments to present information that was long possessed by the movant and that was directly relevant to the litigation." *Alcon Research. Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1192 (Fed. Cir. 2014).

III. DISCUSSION

A. Plaintiffs' Motion for Judgment as a Matter of Law

Plaintiffs move for judgment as a matter of law on two grounds. First, they contend that Fresenius introduced insufficient evidence at trial to sustain the jury's verdict of improper inventorship for claims 2 and 3 of the '646 patent. Second, to the extent that argument fails, Plaintiffs seek judgment as a matter of law that no reasonable jury could find that anyone other than Dr. Sergio Dusci contributed as an unnamed co-inventor to claims 2 and 3, *i.e.*, that the improper inventorship determination was based only on the failure to name Dr. Dusci as an inventor.

1. Evidence of Inventorship

Plaintiffs first assert that Fresenius failed to adduce trial evidence that anyone other than the named inventor, Mr. Pizza, contributed to the conception of the claimed invention of the '646 patent. (D.I. 296 at 6-9). To qualify as an inventor, one must "(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Pannu*, 155 F.3d at 1351; *Hip, Inc. v. Hormel Foods Corp.*, 66 F.4th 1346, 1350 (Fed. Cir. 2023).

In their briefing, Plaintiffs clarify that they "do not dispute that there was evidence from which the jury could have concluded that Dr. Dusci, rather than Mr. Pizza, contributed the claim element concerning the [approximate 6.75 mg/ml] amount of sodium chloride," which is present in claims 2 and 3 of the '646 patent (but not in claim 1). (D.I. 296 at 2). They focus their argument, instead, on whether Fresenius proved that Dr. Dusci's contribution was *significant enough* to qualify him as a co-inventor under the relevant test. *See Pannu*, 155 F.3d at 1351. Specifically, they assert that Dr. Dusci's contribution was (i) "insignificant" when "measured against the dimension of the full invention," and (ii) nothing more than an explanation of a well-known concept in the field. *Id.* The Court addresses Plaintiffs' argument step by step.

a. Mr. Pizza's Contribution as Inventor

The inquiry begins with the contribution of the '646 patent's named inventor, Mr. Pizza, who himself testified that there were important aspects of the Asserted Claims that he "did not personally come up with." (Tr. at 286:1-15). In particular, he conceded that he did not "think of [the invention's] specific amount of calcium gluconate" (19.6 mg/ml) or develop any of its specific

chemical concentrations: calcium saccharate (.9 mg/ml) or sodium chloride (6.75 mg/ml). (*Id*. at 298:22-301:5). Those three limitations comprise all of the additional elements of dependent claim 2 and are incorporated in claim 3, which depends on claim 2. (*See* JTX-1 at 5-6) ("[W]herein the solution comprises [(1)] 19.6 mg/ml of calcium gluconate monohydrate, [(2)] about 0.9 mg/ml of calcium D-saccharate, and [(3)] about 6.75 mg/ml sodium chloride.").

Instead, Mr. Pizza acknowledged that he outsourced nearly all of that work to InfoRLife, including formulating the solution, running tests, and product development. (Tr. at 298:23-311:23). The same goes for the bag's 24-month shelf life, (*id*. at 303:6-304:18), the additional claim element of dependent claim 3. (*See* JTX-1 at 6) ("[W]herein the solution has a shelf [life] of at least about 24 months when stored at 25° C.").

As already mentioned, Plaintiffs do not seriously dispute these facts; they acknowledge that "Mr. Pizza did not determine the amount of the ingredients that are specified in the claimed formulation." (D.I. 296 at 10). Thus, there was uncontested trial evidence that Mr. Pizza did not determine any of these precise claim limitations.[3] A reasonable jury was entitled to wonder, "who did?"

b. Dr. Dusci's Contribution As Co-Inventor

That brings us to Dr. Dusci. Plaintiffs contend that, even if he did determine the invention's formulation, there was no evidence at trial that Dr. Dusci's input was material under the second and third prongs of the *Pannu* test. (D.I. 296 at 7). Plaintiffs hinge their argument on the

[3] There is no dispute that Mr. Pizza was properly listed as an inventor. *See Belcher Pharms., LLC v. Hospira, Inc.*, 450 F. Supp. 3d 512, 546 (D. Del. 2020) ("[The inventor] is a CEO, not a scientist, who directed others to test his general hypotheses. . . . [I]t is not a necessary condition for the inventor of [a chemical] product to possess all of the skills of an advanced pharmaceutical formulator. Nor does the law require that the inventor actually reduce the invention to practice.").

proposition that the only relevant testimony or evidence offered on the point was provided by Fresenius' expert, Dr. Rabinow, who opined that Dr. Dusci played a "pivotal role" in the invention. (Tr. at 704:25-705:3). Plaintiffs say that this testimony only goes to the first prong of the *Pannu* test – whether Dr. Dusci contributed at all – but says nothing of the import of that contribution. (D.I. 307 at 6-7). That position is refuted by other trial testimony and evidence, however.

First, Dr. Rabinow's opinions were not the only evidence offered on this point. Mr. Pizza repeatedly testified that InfoRLife was hired to "implement [the] invention," including to "do the contract manufacturing, do the contract testing, [and] tweaking that formula to make sure we got the results that would be approvable." (Tr. at 289:1-5). Ms. Squeglia said the same thing. (*Id.* at 596:1-597:5, 777:7-782:12). And it was clear from the trial evidence that the InfoRLife team worked "under the direction of Dr. Dusci," who "oversaw" the "implent[ation] [of] the invention." (*Id.* at 317:15-318:17, 585:6-8).

Moreover, with respect to Dr. Rabinow's testimony, he opined that Dr. Dusci "was not just a pair of hands" to carry out instructions; he was a "major" contributor and "certainly should have been considered an inventor." (*Id*. at 704:3-10). Dr. Rabinow went on to explain that is because Dr. Dusci insisted on selecting an osmolality level "to make a drug which is better for the patient," thereby "taking the moral high ground" as to product quality rather than defaulting to the industry standard that Plaintiffs initially wanted to use. (*Id.*). That testimony was based on corroborating test reports showing that Dr. Dusci and InfoRLife had run multiple analyses to arrive at the conclusion that the 6.75 mg/ml sodium chloride concentration was best. (*See* DTX-195). Those opinions constitute substantial evidence that the jury was free to accept or reject. *See MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1168 (Fed. Cir. 2015) ("Here, the jury credited the testimony of [one party's] expert over the testimony of [the other's] expert."); *Kinetic Concepts,*

Inc. v. Smith & Nephew, Inc., 688 F.3d 1342, 1362 (Fed. Cir. 2012) ("Because of this conflicting expert testimony, the jury was free to make credibility determinations and believe the witness it considers more trustworthy.") (internal quotation marks omitted).

Other evidence also shows that there was a disagreement over the precise amount of sodium chloride to use in the invention and that Dr. Dusci played a key role in coming up with the patented quantity. Ms. Squeglia suggested a lower amount, in the "range of 340-400 mOsm/kg[,] which would be in line with how the product is being used now." (DTX 242.001). But Dr. Dusci advocated for a higher concentration: "I do not agree . . . our goal is to have the best product for the patient, not repl[icate] the [current market] situation," and urged the higher concentration "because the [existing] compoundings have not the possibility to have bags of [sodium chloride with] 0.67." (*Id.*). In the end, Mr. Pizza "agreed to" Dr. Dusci's proposed concentration of 6.75 mg/ml sodium chloride. (Tr. at 300:19-301:1, 781:13-17).

Moreover, Plaintiffs originally considered a 9 mg/ml sodium chloride mixture in their formulation based on what was "standard" in the industry. (DTX-77.18-19; Tr. at 781:10-12) ("Q: Was 6.75 milligrams per milliliter a standard amount of sodium chloride to use in a product? A: No. The standard is usually nine."). Dr. Dusci's rejection of that "standard amount" constitutes further substantial evidence that his contribution did "more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Pannu*, 155 F.3d at 1351; *Falana v. Kent State Univ.*, 669 F.3d 1349, 1357 (Fed. Cir. 2012) ("Conception of a chemical compound requires knowledge of both the specific chemical structure of the compound and an operative method of making it.") (internal quotation marks omitted).

Accordingly, the Court finds that there was substantial evidence from which the jury could find that Dr. Dusci made a significant, novel contribution to the patented invention, at least by deriving and implementing the 6.75 mg/ml sodium chloride claim limitation of claims 2 and 3.[4]

2. Other Potential Inventors

Having addressed the inventive contributions of Mr. Pizza and Dr. Dusci, the next question is whether the evidence at trial supports anyone else as a co-inventor on the '646 patent. Plaintiffs say the answer is no and ask the Court to do the same as a matter of law. (D.I. 296 at 9-10). Fresenius appears to concede this point; it offers no response in its briefing. *See CardSoft, LLC v. VeriFone, Inc.*, 807 F.3d 1346, 1353 (Fed. Cir. 2015) ("By failing to respond to [defendant's] argument in the briefing, [plaintiff] has effectively conceded that [point]."). Instead, Fresenius argues that it had no obligation to prove that any specific third-party individual should have been listed as an inventor – only that Mr. Pizza was not properly named as the sole inventor. (D.I. 304 at 6-7); *see also Belcher Pharms., LLC v. Hospira, Inc.*, No. 17-775 (LPS), 2019 WL 2503159, at *1 n.1 (D. Del. June 5, 2019) ("Allegations of statutory invalidity due to improper inventorship also need not be accompanied by the names of the supposed correct inventors. A patent may be invalid simply because it names the wrong inventors."); *LendingTree, LLC v. Zillow, Inc.*, 656 F. App'x 991, 998 (Fed. Cir. 2016) ("[T]he court determined that, based on the evidence before it, there were 'several combinations of inventors' that the jury could have reasonably concluded should be listed on the patents in suit (instead of the originally listed inventors)."); *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1381 (Fed. Cir. 2000).

[4] Because the Court determines that Dr. Dusci's contribution of the 6.75 mg/ml of sodium chloride is sufficient to make him an inventor of claims 2 and 3, the Court does not address the remaining additional elements of those claims.

Although it may be true that Fresenius could succeed on its improper inventorship argument by identifying just one unnamed inventor, the fact is that nothing precluded Fresenius from asserting that others were also left off. It chose not to, and, as a result, there is no evidence before the Court that the jury's improper inventorship verdict was supported by unacknowledged inventive contributions by anyone other than Dr. Dusci. Therefore, the Court grants Plaintiffs' motion for judgment as a matter of law that Fresenius failed to present substantial evidence at trial that anyone other than Mr. Pizza and Dr. Dusci made inventor-worthy contributions to the '646 patent.

B. Fresenius' Motion for Judgment As a Matter of Law or New Trial

Having resolved Plaintiffs' motion for judgment as a matter of law, the Court next turns to Fresenius' motions. First, Fresenius contends that it is entitled to judgment as a matter of law that the '646 patent was obvious. Second, in the alternative, Fresenius contends that it deserves a new trial due to three discrete errors made over the course of the trial.

1. Judgment As a Matter of Law

Fresenius challenges the jury's verdict of non-obviousness of the '646 patent. Specifically, Fresenius contends that the only findings a reasonable jury could make were that (1) the claimed invention was obvious due to a clear motivation to combine and reasonable expectation of success, and (2) Plaintiffs' secondary considerations of non-obviousness fail to rebut that prima facie case. (D.I. 294). Plaintiffs counter that they presented evidence sufficient for the jury to determine that there was no reasonable expectation of success or motivation to combine, and, moreover, that the claimed invention was commercially successful, responded to a long-felt need in the industry, and was later copied by Fresenius. (D.I. 305).

An accused infringer may escape liability by proving by clear and convincing evidence that the patent at issue is obvious. *See* 35 U.S.C. § 103. "Obviousness is a question of law based on underlying findings of fact." *Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1356-57 (Fed. Cir. 2018). A jury verdict of obviousness must be supported by facts of "(1) the scope and content of the prior art, (2) differences between the prior art and the claims at issue, (3) the level of ordinary skill in the pertinent art, and (4) the presence of objective indicia of nonobviousness such as commercial success, long felt but unsolved needs, failure of others, and unexpected results." *Cyntec Co., Ltd. v. Chilisin Elecs. Corp*., 84 F.4th 979, 984 (Fed. Cir. 2023) (citation omitted). "The ultimate question is whether differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious to a person of ordinary skill in the pertinent art at the time of the invention." *LKQ Corp. v. GM Glob. Tech. Operations LLC*, 102 F.4th 1280, 1291 (Fed. Cir. 2024).

"A party seeking to invalidate a patent on obviousness grounds must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1344 (Fed. Cir. 2021) (citation modified). Those too are questions of fact. *See Cyntec*, 84 F.4th at 984; *Osseo Imaging, LLC v. Planmeca USA Inc.*, 116 F.4th 1335, 1344 (Fed. Cir. 2024). "Where, as here, the jury made no explicit factual findings regarding obviousness, [the Court] must determine whether the implicit findings necessary to support the verdict are supported by substantial evidence." *Osseo Imaging*, 116 F.4th at 1344 (citation omitted).

a. Reasonable Expectation of Success

Fresenius first argues that the claimed invention is obvious because a skilled artisan would have had a reasonable expectation of success in crafting it. (D.I. 294 at 7-10).

At trial, Plaintiffs' expert, Dr. Zhao, opined that "there is no reasonable expectation of success" when asked whether a skilled artisan in 2017 "could take the calcium gluconate, the calcium saccharate, the other [components], dilute it, put it in a flexible plastic bag and subject it to terminal sterilization to get a product where it could be stable."[5] (Tr. at 832:25-833:6, 845:11-22) ("[T]here is no reasonable expectation of success considering all the uncertainties [and] risks I [just] explained to you."). In support of that testimony, Dr. Zhao explained that transmuting the extant compounded vial calcium gluconate products into pre-mixed bags carried "increased risks for chemical stability issue[s] [and] physical stability issue[s], not only during [the] autoclaving process, [but also] during the 24-month storage period at room temperature afterwards." (*Id.* at 825:18-22). This is because, from a chemical standpoint, "[d]ilution actually has multiple potential [types of] risks," including "a high risk for potential serious instability." (*Id.* at 828:19-829:3). As to packaging and sterilization, moreover, Dr. Zhao opined that, "every time you change [the] packaging material, especially for solutions, you significantly increase the risk," additionally acknowledging that "terminal sterilization raises potential problems for a formulator." (*Id.* at 830:23-831:17). This evidence was sufficient for a reasonable jury to doubt that a person of skill in the art would have had a reasonable chance of succeeding in creating the claimed invention. *See Cumberland Pharms. Inc. v. Mylan Inst. LLC*, 846 F.3d 1213, 1223 (Fed. Cir. 2017) ("[T]here was testimony explaining that a person of ordinary skill would not expect [the claimed formulation] to remain stable.")

[5] The parties stipulated to the definition of skilled artisan in this case. (*See* Tr. at 610:22-611:15, 909:7-910:5; D.I. 314 at 8).

Fresenius attacks Dr. Zhao's opinions as legally insufficient on four grounds. First, it says that her testimony was based on the wrong legal standard because it relied on "uncertainty" rather than "reasonable" success. (D.I. 294 at 13-14). As laid out in the preceding paragraph, however, Dr. Zhao detailed the "issues" and "risks" inherent in the formulation, packaging, and sterilization components of Plaintiffs' calcium gluconate bag. She did not rely on the wrong standard. *See Cumberland Pharms.*, 846 F.3d at 1222 ("Considerable evidence supports the finding that relevant skilled artisans . . . had no reasonable expectation of [chemical] stability" due to certain "risk," "vulnerab[ility]," and "sensitiv[ity].").

Second, Fresenius argues that Dr. Zhao's testimony was not credible and "contradicted by other evidence." (D.I. 308 at 5). It is the duty of the jury to make credibility determinations, though, not the Court, and "when there is conflicting testimony at trial, and the evidence overall does not make only one finding on the point reasonable, the jury is permitted to make credibility determinations and believe the witness it considers more trustworthy." *MobileMedia*, 780 F.3d at 1168 ("[S]ubstantial evidence supports the jury's finding that one of skill in the art would not have been motivated to combine."). Thus, "[i]t was ultimately up to the jury, [here], to weigh the credibility of the parties' opposing theories and evidence." *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1378 (Fed. Cir. 2003).

Next, Fresenius contends that other evidence suggested that there was a reasonable expectation of success. (D.I. 294 at 11-12). Fresenius principally points to testimony from its expert, Dr. Rabinow, that terminally sterilized vials and bags were both known in the field and prior art. (*See, e.g.*, Tr. at 682:17-683:12, 699:12-700:2, 721:14-24). Thus, in essence, Dr. Rabinow testified that there was a reasonable expectation of success and Dr. Zhao testified that there was not. This "classic example of competing experts," where the jury was able to choose

"which expert's analysis they believed," constitutes "substantial evidence." *Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1394 (Fed. Cir. 2003). And "[b]y finding in favor of [patentee], the jury impliedly found [patentee's] expert's testimony more credible and persuasive than the testimony proffered by [the accused infringer]." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1062 (Fed. Cir. 2016).

Finally, Fresenius argues that there was a reasonable expectation of success because premixed products were preferred, terminal sterilization was obvious, and Plaintiffs' calcium gluconate bag merely combined known prior art. (D.I. 294 at 10-13). Each of those is a factual conclusion – precisely what the jury was empaneled to decide. The Court's "job is not to review whether [one side's] losing position was also supported by substantial evidence or to weigh the relative strength of [that party's] evidence against [the other's] evidence." *Apple v. Samsung*, 839 F.3d at 1052. Instead, the Court is limited to determining whether, on the entirety of the record, there was substantial evidence underpinning the jury's findings. *Id.* Here, there was.

b. Motivation to Combine Prior Art References

Fresenius next argues that Plaintiffs' calcium gluconate bag was obvious because a skilled artisan would have been motivated to combine prior art references to form the claimed invention. As with reasonable expectation of success, the parties' experts sparred on this point.

Dr. Zhao opined that a skilled artisan would not have been motivated to combine, because the prior art references "don't teach terminal sterilization of the new [chemical] composition that has the diluted calcium gluconate, diluted calcium saccharate with the addition of [a] new tonicity agent [all] put [together] into a new packaging component . . . So new composition, new packaging material, and then terminally sterilize that, . . . with a product that is stable at room temperature for 24 months. To combine these[,] [the] prior arts don't teach that." (Tr. at 844:5-13). In the

same vein, Dr. Zhao acknowledged that she was unaware of anyone who had created a terminally sterilized bag with a two-year shelf life prior to the claimed invention. (*Id.* at 845:5-10).

By contrast, Dr. Rabinow testified that "the prior art would be combined." (*Id*. at 698:11-18). Fresenius says that opinion was supported by "overwhelming evidence," such as FDA guidance, the laboratory manual, and other expert and lay witness trial testimony. (D.I. 294 at 8). But, again, the test here is not whether there was substantial trial evidence to prove Fresenius' case; it is whether there was an absence of substantial evidence to support Plaintiffs'. And, once again, the battle of the experts here provided enough for a reasonable jury to conclude either way. *See Micro Chem.*, 317 F.3d at 1394; *Apple v. Samsung*, 839 F.3d at 1062.

c. Secondary Considerations of Non-Obviousness

"Objective indicia of nonobviousness must be considered in every case where present." *Apple v. Samsung*, 839 F.3d at 1048. "Objective evidence of nonobviousness includes: (1) commercial success, (2) copying, (3) industry praise, (4) skepticism, (5) long-felt but unsolved need, and (6) failure of others." *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1212 (Fed. Cir. 2023).

Here, even if Fresenius had proved a reasonable expectation of success or motivation to combine, there was substantial evidence upon which the jury could have reasonably found that obviousness rebutted by secondary indicia such as the invention's (1) commercial success, (2) long-felt need, and (3) copying. *See Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356, 1365 (Fed. Cir. 2013) ("[O]bjective evidence of secondary considerations . . . must be considered before determining whether the claimed invention would have been obvious to one of skill in the art at the time of invention.").

i. Commercial Success

The parties do not dispute that Plaintiffs' calcium gluconate bag was successful. Instead, they contest whether that success was attributable to any particular feature or aspect of the patented invention – known as "nexus." At the outset, it is worth noting that "nexus is presumed when a commercial product (if relevantly successful, for example) is the invention disclosed and claimed in the patent." *Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1363 (Fed. Cir. 2023) (internal quotation marks omitted). At trial, however, Plaintiffs presented evidence of nexus. For instance, their expert Mr. McGahee opined that there was a demonstrated "demand" in the market for the product's features: "terminally sterilized[,] premixed[,] ready to administer bag[,] with a long shelf life." (Tr. at 355:12-357:22). That expert testimony was consistent with lay witness testimony and documentary evidence that highlighted the benefits of those features, such as reducing the risks of contamination, mitigating human error, and minimizing labor. (*Id.*; *see also id*. at 197:10-20; PTX-155.001, 174.020-29; DTX-665).

Fresenius counters that customers preferred the prior art vial product, and, additionally, that Plaintiffs' commercial success was due to discounting rather than the bags' attributes. (D.I. 294 at 15-16). Fresenius' preference argument is contradicted by its earlier contention that premixed bags were preferred by the market. (*Id.* at 10). As to pricing, trial evidence from multiple witnesses characterized Plaintiffs' bags as having been sold at a "premium price to the [competing] vial." (*See, e.g.*, Tr. at 217:21-24, 238:21-239:11). On the basis of that evidence, the jury was entitled to find that Fresenius did not rebut the presumption of nexus and that the commercial success of Plaintiffs' premixed bags preempted a finding of obviousness.

ii. Long-Felt Need

As to long-felt need, Plaintiffs offered evidence that there have been concerns about the safety of compounding since the 1970s, that the FDA publishes warnings about compounding health risks, and that various contaminated compounding outbreaks since 2012 resulted in dozens of fungal infection deaths. (*See* PTX-67; Tr. at 802:17-805:9). Fresenius contends that its vial product outperformed bag sales in the market, undercutting long-felt need, and, moreover, that the trial evidenced failed to show a specific problem or efforts to correct it. (D.I. 294 at 16-17; D.I. 308 at 8-9).

The jury was free to weigh Plaintiffs' safety evidence against Fresenius' financial evidence and find that, notwithstanding successful prior art vial sales and some shared components of the products, there was still a long-felt need for a terminally sterilized calcium gluconate bag product. *See Apple v. Samsung*, 839 F.3d at 1056 ("There could be a long-felt need for what might be considered a relatively small improvement over the prior art – it all depends upon the evidence, and it is up to the fact finder to assess that evidence."). To that same point, the trial testimony did identify a specific problem – the risks of contamination in compounding and resulting harm to patients. And, finally, all experts were in agreement that no competitor had tried to launch a calcium gluconate bag product before Plaintiffs. (*See* Tr. at 514:16-18, 712:15-717:11). That provided a sufficient basis for the jury to conclude that there was a long-felt but unmet need for terminally sterilized ready-to-use calcium gluconate bags.

iii. Copying

"It is well established that copying by a competitor is a relevant consideration in the objective indicia analysis. [Because] copying may be evidence that the patented invention is nonobvious." *Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1137 (Fed. Cir. 2019)

(internal citation omitted). Plaintiffs presented documentary and testimonial evidence at trial from Fresenius personnel stating that "we are essentially copying [Plaintiffs'] product." (PTX-149.001; PTX-147.001; PTX-193.016; Tr. at 563:23-566:13, 757:3-762:7). Fresenius again counters that Plaintiffs failed to prove nexus – that Fresenius copied the novel aspects of the claimed invention. (D.I. 294 at 17); *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012). But, as Plaintiffs point out, Fresenius' Accused Product copies substantially every one of the four claim limitations of Plaintiffs' calcium gluconate bag. And although Fresenius asserts that it simultaneously invented the Accused Product, trial testimony brought out that Fresenius "started the development work after [Plaintiffs] already got approved" by the FDA, and that it had done no testing up to that point. (Tr. at 571:16-572:9, 762:8-20).

Thus, there was sufficient evidence upon which the jury could find that Fresenius copied the claimed invention, thereby undermining Fresenius' prima facie case of obviousness.

* * * * *

In sum, the jury could reasonably find that the claimed invention of the '646 patent was not obvious. First, there was substantial evidence that a skilled artisan would not have had a reasonable expectation of success or motivation to combine. And, second, Plaintiffs "presented considerable record evidence on objective indicia, including . . . copying, commercial success, . . . and long-felt need." *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1379 (Fed. Cir. 2012). Fresenius' motion for judgment as a matter of law is, therefore, denied.

2. Motion for a New Trial

In the alternative, Fresenius moves for a new trial. It advances three reasons for why it believes it deserves one. First, it says that the jury's verdict with respect to non-obviousness was against the great weight of the evidence, substantially for the reasons advanced in its motion for judgment as a matter of law. (D.I. 294 at 19). Second, Fresenius asserts that Plaintiffs improperly

sowed jury confusion at various points during the trial. (*Id.*). And, third, Fresenius contends that the jury was given an improper instruction on the law of obviousness. (*Id.* at 19-20). The Court is unpersuaded by any of the three and will deny the motion for a new trial.

a. The Weight of the Evidence

Fresenius first contends that the jury's verdict was against the great weight of the evidence for the same reasons set forth in its motion for judgment as a matter of law. (D.I. 294 at 19). "Although the standard for granting a new trial is less rigorous than the standard for granting judgment as a matter of law – in that the court need not view the evidence in the light most favorable to the verdict winner – a new trial should only be granted where a miscarriage of justice would result if the verdict were to stand, the verdict cries out to be overturned, or the verdict shocks the conscience." *Ateliers*, 85 F. Supp. 3d at 776 (citation modified). The Court finds that the jury's verdict does no such thing, substantially for the same reasons that the Court declined to upset the jury's verdict in Fresenius' motion for judgment as a matter of law. *See Northpoint Tech., Ltd. v. MDS Am., Inc.*, 413 F.3d 1301, 1311 (Fed. Cir. 2005). Its request for a new trial on these same grounds is therefore denied.

b. Alleged Jury Confusion

Fresenius next contends that Plaintiffs' counsel "intentionally injected confusion" into the jury's view of the law and facts with improper statements made during opening and closing arguments. (D.I. 294 at 19). Effectively, Fresenius says that counsel mischaracterized the law on obviousness and misrepresented the record with respect to certain statements made to the FDA. (*Id.*) (citing Tr. at 138:24-139:2, 151:5-25, 944:14-20, 986:20-25). Neither is sufficient to warrant a new trial, however.

The jury was instructed that statements by counsel are not evidence, and, additionally, was given the proper instruction on the law on obviousness (more on that in the following section). (*See* Tr. at 97:23-98:8, 911:13-915:5). Those instructions were legally sufficient to ameliorate any confusion the jury might have had. *See Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop., Inc.*, 89 F.4th 430, 446 (3d Cir. 2023); *White v. City of Vineland*, No. 22-3204, 2024 WL 4707994, at *3 (3d Cir. Nov. 7, 2024).

Just as important, Fresenius did not object to any of the challenged statements at the time they were made. "[A] party who fails to object to errors at trial waives the right to complain about them following trial." *Waldorf v. Shuta*, 142 F.3d 601, 629 (3d Cir. 1998); *Murray v. Fairbanks Morse*, 610 F.2d 149, 152 (3d Cir. 1979) ("Counsel's failure to object precludes him from seeking a new trial on the grounds of the impropriety of opposing counsel's closing remarks."); Fed. R. Evid. 103(a). Thus, because it "failed to lodge a contemporaneous objection" at trial, Fresenius "has waived such an objection." *Leonard v. Stemtech Int'l Inc*, 834 F.3d 376, 401 (3d Cir. 2016).

Even if Fresenius had timely objected, "the party seeking a new trial must demonstrate that the attorney's conduct constitutes misconduct, and not merely aggressive advocacy, and that the misconduct is prejudicial in the sense of affecting a substantial right in the context of the entire trial record." *Lucent Techs., Inc. v. Newbridge Networks Corp.*, 168 F. Supp. 2d 181, 260 (D. Del. 2001). Here, Fresenius asserts that Plaintiffs' counsel misstated the law. Even if true, "[t]he Court is not convinced that those statements were misconduct as opposed to aggressive advocacy." *Bd. of Regents v. Bos. Sci. Corp.*, No. 18-392 (GBW), 2024 WL 2848471, at *15 (D. Del. June 5, 2024). Nor does Fresenius identify a "substantial right" that was offended or problem that would have tainted "the entire trial record." *Lucent*, 168 F. Supp. 2d at 260. In other words, "the allegedly improper statements or conduct [do not] make it 'reasonably probable' that

the verdict was influenced by the resulting prejudice." *Forrest v. Beloit Corp.*, 424 F.3d 344, 351 (3d Cir. 2005). Therefore, Fresenius may not retry this case on the basis of opposing counsel's statements.

c. The Court's Jury Instructions

Finally, Fresenius asserts that the Court improperly instructed the jury as to obviousness. (D.I. 294 at 19-20). Specifically, Fresenius says that the Court erred in rejecting its request for an instruction that "you should also consider whether any evidence relating to invalidity is materially new to the evidence considered by the Patent Office. Where the Patent Office did not previously have all the material facts before it, Fresenius' burden to prove invalidity by clear and convincing evidence may be easier to sustain." (Tr. at 883:19-884:17). Fresenius argues that it was prejudiced by the omission of this instruction, which would have allowed the jury to find obviousness based on the FK 2017 Label not being submitted to the PTO. (D.I. 294 at 20).

To obtain a new trial, "a party challenging jury instructions must prove the jury instructions read in their entirety were incorrect or incomplete as given." *Eko Brands, LLC v. Adrian Rivera Maynez Enters., Inc.*, 946 F.3d 1367, 1378 (Fed. Cir. 2020) (internal quotation marks omitted). The Court "only orders a new trial when errors in the instructions as a whole clearly mislead the jury." *SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1379 (Fed. Cir. 2013). "Moreover, a jury verdict will [only] be set aside, based on erroneous jury instructions, if the movant can establish that those instructions were legally erroneous and that the errors had prejudicial effect."[6] *Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1278

[6] Federal Circuit law governs the propriety of jury instructions on a patent issue, rather than Third Circuit law. *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004); *Eko Brands*, 946 F.3d at 1378.

(Fed. Cir. 2011) (internal quotation marks omitted). Fresenius fails to establish that the instructions were erroneous, misleading, or prejudicial.

To begin, the Court's instruction, which largely tracks the Federal Circuit's Model Jury Instructions, correctly states the law on obviousness. *See Robinson v. First State Cmty. Action Agency*, 920 F.3d 182, 190 (3d Cir. 2019) ("[I]t is unlikely that the use of a model jury instruction can constitute error.") (citation modified); *Forrest v. Parry*, 930 F.3d 93, 119 n.16 (3d Cir. 2019). In addition, Fresenius fails to explain how the "instructions as a whole clearly misle[d] the jury." *SynQor*, 709 F.3d at 1379; *Sulzer Textil*, 358 F.3d at 1364 ("When the error in a jury instruction could not have changed the result, the erroneous instruction is harmless.") (internal quotation marks omitted).

Second, Fresenius asserts that it was prejudiced because the Court's instruction caused it to face "a harder threshold to meet" on obviousness. (D.I. 308 at 10). But, as the case law has repeatedly emphasized, "there is no heightened or added burden that applies to invalidity defenses that are based upon [the] references that were [or were not] before the Patent Office. The burden is always the same, clear and convincing evidence." *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012) ("Whether a reference was previously considered by the PTO, the burden of proof is the same: clear and convincing evidence of invalidity."); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 109 (2011) ("Nothing in § 282's text suggests that Congress meant . . . to enact a standard of proof that would rise and fall with the facts of each case.").

Accordingly, and as the Court noted at the time, Fresenius' proposed instruction would be more confusing to the jury than helpful. (*See* Tr. at 884:10-17). In any event, Fresenius was fully heard on its argument that the prior art was not properly presented to the PTO during prosecution of the '646 patent – that was squarely the subject of the bench trial on inequitable conduct.

(*See* D.I. 314). Therefore, the Court finds that Fresenius suffered no prejudice, a new trial is not warranted on this ground, and Fresenius' motion is denied.

C. Plaintiff's Motion to Correct Inventorship

In light of the verdict that claims 2 and 3 of the '646 patent are invalid for lack of proper inventorship, Plaintiffs move to correct inventorship under 35 U.S.C. § 256(b). They seek to add Dr. Dusci as a named inventor on the patent. "[I]nventorship can be corrected at any time." *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 988 F.2d 1157, 1162 (Fed. Cir. 1993). "If a patentee demonstrates that inventorship can be corrected as provided for in section 256, a district court must order correction of the patent, thus saving it from being rendered invalid." *Pannu*, 155 F.3d at 1350.

Fresenius contests correction on two grounds: (i) that Plaintiffs' affidavits lack elements necessary for correction; and (2) that the doctrine of judicial estoppel bars the correction. (D.I. 281). At the outset, Plaintiffs suggest in a footnote in their reply brief that Fresenius lacks standing to challenge correction here on the basis that only "named inventors, omitted inventors, and assignees" constitute "concerned parties" for the purposes of correction. (D.I. 292 at 1 n.1). "[A]rguments raised in passing (such as, in a footnote), but not squarely argued, [however,] are considered forfeited." *Higgins v. Bayada Home Health Care Inc.*, 62 F.4th 755, 763 (3d Cir. 2023) (citation modified); *Kalu v. Spaulding*, 113 F.4th 311, 344 n.21 (3d Cir. 2024).

In any event, Plaintiffs' standing argument is foreclosed as a matter of law by Federal Circuit precedent, which has explained that "an expectation of ownership of a patent is not a prerequisite for a [party] to possess standing to [litigate] correct inventorship under § 256." *Chou v. Univ. of Chicago*, 254 F.3d 1347, 1358 (Fed. Cir. 2001). Instead, "parties with an economic stake in a patent's validity are entitled to be heard on inventorship issues." *Id.* at 1359;

Doda v. Waste Mgmt., Inc., No. 17-604 (CFC), 2019 WL 4671190, at *2 (D. Del. Sept. 25, 2019). That is because "[t]he interest of both inventors and the public are [equally] served by a broad interpretation of the statute." *Chou*, 254 F.3d at 1358; *Pei-Herng Hor v. Ching-Wu Chu*, 699 F.3d 1331, 1336 (Fed. Cir. 2012). Such is the case here, where Fresenius has a "concrete financial interest" in the outcome of this motion and litigation, including Plaintiffs' Rule 59 motion to alter the judgment. *Larson v. Correct Craft, Inc.*, 569 F.3d 1319, 1326 (Fed. Cir. 2009). Thus, the Court finds Fresenius has standing to challenge correction under § 256 and will evaluate its arguments.

1. The Affidavits of Correction

As required by 37 C.F.R. § 1.324(b), Plaintiffs submitted sworn statements from Mr. Pizza, Dr. Dusci, and HQ consenting to the correction. (*See* D.I. 269, 270, 271). Fresenius argues that these affidavits are flawed for two reasons.

First, Fresenius asserts that the omission of Dr. Dusci as a co-inventor was made intentionally by Mr. Pizza and HQ, rather than "through error," and, therefore, the '646 patent is ineligible for correction. (D.I. 281 at 9-10); 35 U.S.C. § 256(a); 37 C.F.R. § 1.324(a). As Plaintiffs rightly point out, however, that is not the current state of the law. (D.I. 292 at 7-8). Federal Circuit "precedent provides that 'error' in § 256 includes all varieties of mistakes – honest and dishonest – rather than only unintentional inaccuracy." *Egenera*, 972 F.3d at 1376 (some quotation marks omitted). Thus, "§ 256 does not exclude considered acts, or even deceptive intentions from the meaning of 'error.'" *Id*. at 1377 (internal quotation marks omitted). Simply put, the Federal Circuit's "broad interpretation" has "expressly construed 'error' to embrace more than simply honest mistakes." *Id.* (internal quotation marks omitted); *CODA Dev. S.R.O. v. Goodyear Tire & Rubber Co.*, 916 F.3d 1350, 1358 n.6 (Fed. Cir. 2019). Accordingly, even if Plaintiffs did

intentionally omit Dr. Dusci as a co-inventor – a finding the Court rejected in its bench trial opinion and declines again to make today – that would have no impact on the correction analysis. (*See* D.I. 314 at 26-27).

Second, Fresenius argues that the affidavits contain "conditional" assertions that "qualify" Dr. Dusci's contribution to the invention and therefore cannot satisfy compliance under Section 256. (D.I. 281 at 10-11; *see also* D.I. 269 ¶¶ 6-7; D.I. 270 ¶¶ 7-8). Although the Court takes Fresenius' point – the affidavits are unusually worded – it does not change the outcome. Fresenius is correct that "[a]n alleged joint inventor's testimony alone is insufficient to establish inventorship by clear and convincing evidence." *BearBox*, 125 F.4th at 1117. There must be "evidence to corroborate his testimony," such as "contemporaneous documents or physical evidence, circumstantial evidence about the inventive process, [or] oral testimony of someone other than the alleged inventor." *Id.* at 1118 (citation modified).

Here, Plaintiffs' declarations do not stand alone. As has already been discussed at length above, *see* Section III(A)(1)(b), *supra*, substantial evidence demonstrates that Dr. Dusci offered material input on key limitations of claims 2 and 3 for Plaintiffs' calcium gluconate bags while "working under common direction" from HQ personnel. *BearBox*, 125 F.4th at 1118 (citation omitted). Documents, testimony, and expert opinions were all offered in support of that conclusion. *Id.* For that same reason, the Court is unpersuaded by Fresenius' additional arguments that the declarations fail to point to record evidence, show the degree of Dr. Dusci's contribution, or "confirm that Dr. Dusci is the only non-joined inventor." (D.I. 281 at 11-14). As the Court found earlier, there is no evidence that anyone other than Mr. Pizza and Dr. Dusci contributed to the claimed invention, and Fresenius did not offer any when given the chance in its briefing. *See* Section III(A)(2), *supra*.

Thus, the Court finds that Plaintiffs' declarations are sufficient for the purposes of correction under the statute.

2. Judicial Estoppel

Fresenius also maintains that Plaintiffs should be judicially estopped from asserting that Dr. Dusci is a named inventor because it argued the contrary at trial and in their briefing for judgment as a matter of law. (D.I. 281 at 14). "When properly invoked, judicial estoppel bars a litigant from asserting a position that is inconsistent with one he or she previously took before a court or agency." *Montrose Med. Grp. Participating Sav. Plan v. Bulger*, 243 F.3d 773, 779 (3d Cir. 2001). However, "judicial estoppel is an extreme remedy, to be used only when the inconsistent positions are tantamount to a knowing misrepresentation to or even fraud on the court." *Chao v. Roy's Const., Inc.*, 517 F.3d 180, 186 n.5 (3d Cir. 2008) (internal quotation marks omitted). And "judicial estoppel is generally not appropriate where the defending party did not convince the [presiding] Court to accept its earlier position." *G-I Holdings, Inc. v. Reliance Ins. Co.*, 586 F.3d 247, 262 (3d Cir. 2009).

In the Third Circuit, a party seeking judicial estoppel must establish three factors. "First, the party to be estopped must have taken two positions that are irreconcilably inconsistent." *Montrose Med. Grp.*, 243 F.3d at 779. "Second, judicial estoppel is unwarranted unless the party changed his or her position in bad faith – i.e., with intent to play fast and loose with the court." *Id.* (internal quotation marks omitted). "Finally, a district court may not employ judicial estoppel unless it is tailored to address the harm identified and no lesser sanction would adequately remedy the damage done by the litigant's misconduct." *Krystal Cadillac-Oldsmobile GMC Truck, Inc. v. Gen. Motors Corp.*, 337 F.3d 314, 319 (3d Cir. 2003) (citation modified).

At the outset, the Court appreciates the odd posture here; both sides find themselves in contradictory positions as a result of simultaneously litigating motions for judgment as a matter of law, on the one hand, and correction of inventorship, on the other. For the first motion, as already discussed, Fresenius was tasked with defending the jury verdict by touting Dr. Dusci's relevant contributions to the invention, while Plaintiffs sought to show that Mr. Pizza was properly listed as the lone inventor and tried to minimize Dr. Dusci's role. Now, on the inventorship motion, the positions are flipped. It is Plaintiffs who must argue that Dr. Dusci was indisputably a co-inventor, while Fresenius must explain away his input as trivial. In that way, the parties are forced to play with Schrodinger's Cat – they address alternate possibilities at the same time.[7] Thus, because the parties have swapped positions, and Plaintiffs' earlier argument was rejected, the Court does not find that Plaintiffs' tactics were nefarious, fraudulent, or undertaken in bad faith. *See Montrose Med. Grp.*, 243 F.3d at 778 ("[A] party has not displayed bad faith for judicial estoppel purposes if the initial claim was never accepted or adopted by [the] court.").

Moreover, Fresenius' estoppel position presents broader issues with the law of correction. As the Federal Circuit has observed, "[i]f [the estoppel] argument were accepted, it is hard to see how ***any*** inventorship correction could occur under § 256." *Egenera*, 972 F.3d at 1379 n.7 (emphasis in original). "By definition, a request to change inventorship would be inconsistent with the 'position' taken at the outset of prosecution, in which inventor names are submitted with the application. And serial petitions would be impossible." *Id*. This Court agrees.

Plaintiffs' motion to correct the inventorship of claims 2 and 3 of the '646 patent to reflect Dr. Dusci as a co-inventor is therefore granted. *See Viskase Corp. v. American Nat'l Can Co*.,

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[7] The Court has now foreclosed one set of outcomes by addressing the motions for judgment as a matter of law: evidence abounds that Dr. Dusci contributed to the invention of the '646 patent. *See* Section III(A)(1)(b), *supra*.

261 F.3d 1316, 1329 (Fed. Cir. 2001) ("[T]he correction of inventorship does not affect the validity or enforceability of the patent for the period before the correction.").

D. Plaintiffs' Motion to Alter the Judgment

Finally, Plaintiffs move to amend the judgment of invalidity under Rule 59(e). (*See* D.I. 277 ¶ 1). Having prevailed on their motion to correct inventorship, they argue that the Court should alter the judgment to reflect that the '646 patent is not invalid for lack of improper inventorship. (D.I. 296 at 11-12). The Court will grant the motion.

"A court may order a correction of inventorship 'on notice and hearing of all parties concerned.'" *Baxalta Inc. v. Bayer Healthcare LLC*, No. 17-1316 (RGA), 2021 WL 1063099, at *1 (D. Del. Mar. 18, 2021) (quoting 35 U.S.C. § 256(b)); *Egenera*, 972 F.3d at 1376. "The error of omitting inventors . . . shall not invalidate the patent in which such error occurred if it can be corrected." 35 U.S.C. § 256; *Viskase*, 261 F.3d at 1329.

Here, "absent a[n amendment], the judgment of invalidity will remain in place, which would appear to violate the letter and spirit of § 256, for one or more alleged errors will have invalidated the patents in suit notwithstanding that they [now] have been[] fully corrected." *LendingTree*, 656 F. App'x at 999.

Accordingly, having found that Plaintiffs have corrected the defect in the inventorship that led to the jury's verdict, the Court will grant Plaintiffs' motion to alter the judgment to reflect that the '646 patent is no longer invalid. An amended judgment will issue following this Memorandum Opinion.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' renewed motion for judgment as a matter of law (D.I. 295) is GRANTED-IN-PART and DENIED-IN-PART, Defendant's motion for judgment as

a matter of law or new trial (D.I. 293) is DENIED, Plaintiffs' motion to correct inventorship (D.I. 267) is GRANTED, and Plaintiffs' motion to alter the judgment (D.I. 295) is GRANTED. An appropriate order will follow.